



PATENT
Attorney Docket No. 219974
DHHS Case E-189-1989/3-US-04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Anderson et al.

Application No. 10/701,022

Filed: November 4, 2003

Reissue of U.S. Patent No. 5,399,346
Issued March 21, 1995

Assigned to: The United States of
America as represented by the
Department of Health and Human
Services

For: Gene Therapy

SUPPLEMENTAL REISSUE DECLARATION AND POWER OF ATTORNEY

1. The contents of the above-identified specification, including the claims, have been reviewed by the assignee.
2. The assignee hereby acknowledges the duty to disclose information that is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.
3. The assignee makes this declaration in support of a reissue of the above-identified U.S. patent, which has been the subject of Interference Nos: 103,708; 104,710; 104,711; 104,712; 104,713; 104,714; and 104,715.
4. The assignee believes the patent to be partly invalid by erroneously claiming without deceptive intent more than the patentees had the right to claim.

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5. The patent is partly invalid because original claims 1, 2-6, 8-11, 13 and 14 are too broad. Specifically, claim 1, and dependent claims 2-6, 8-11, 13 and 14, are too broad because claim 1 recites "a therapeutic protein."
6. In view of the above, claims 1-14 have been canceled and claims 15, 20, 25, 26, 30, and 31 have been added. Claims 15, 20, 25, 26, 30, and 31 are no broader than originally issued claim 1. Claim 15, the broadest claim of the instant application, corresponds substantially to claims 1, 5, and 12 of the originally issued patent. Claim 15 is additionally supported by the patent specification at, for example, column 13, line 1. Claims 20, 25, and 26 correspond to claims 6, 13, and 14 of the originally issued patent, respectively. Claim 30 is supported by the patent specification at, for instance, column 5, lines 21-23, and claim 31 is supported by the patent specification at, for instance, column 17, line 60, to column 18, line 1.
7. The error in the patent, namely the inadvertent claiming of the invention more broadly than the patentees had a right to claim the invention, is the result of error, without deceptive intent, on the part of the patentees. The error arose at the time that the patent application was prosecuted as a result of the failure to appreciate the impact on patentability of two prior art references, namely, Anderson et al., "*The ADA Human Gene Therapy Clinical Protocol*," (submitted to the Department of Health & Human Services on July 6, 1990), Human Gene Therapy, 1:331-332 (1990) (hereinafter "the ADA Protocol") and Rosenberg et al., "*Gene therapy of patients with advanced cancer using tumor infiltrating lymphocytes transduced with the gene coding for tumor necrosis factor*" (submitted to the Department of Health & Human Services on July 6, 1990) (hereinafter "the TNF Protocol").
8. The error was discovered after issuance of the patent, as a result of an interference proceeding involving the patent (specifically, Interference No. 104,712). In that interference proceeding, the Board of Patent Appeals and Interferences determined that (i) originally issued claims 1-5, 8, and 9 of U.S. Patent No. 5,399,346 are unpatentable as anticipated by the ADA Protocol and (ii) that originally issued claims 1-6, 8-11, 13, and 14 are unpatentable as anticipated by the TNF Protocol.

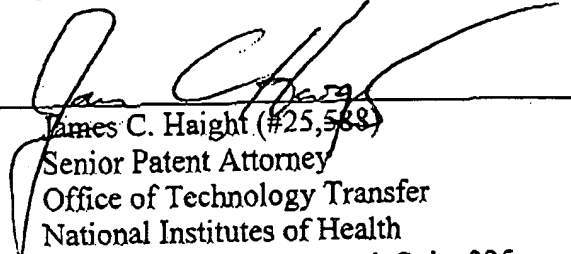
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9. Accordingly, the process claims of the instant reissue application have been amended in view of the disclosure of the ADA Protocol and in view of the disclosure of the TNF Protocol.
10. Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant.
11. The assignee hereby appoints the attorneys and patent agents of the National Institutes of Health, Office of Technology Transfer, and of Leydig, Voit & Mayer, Ltd. who are identified with the following Customer Number, to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith:
- 45733
12. I further direct that correspondence concerning this application be directed to Leydig, Voit & Mayer, Ltd. as Customer Number:
- 45733
13. I declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

The Government of the United States of America,
as delegated to

By:


James C. Haight (#25,588)

Senior Patent Attorney

Office of Technology Transfer

National Institutes of Health

6011 Executive Boulevard, Suite 325

Rockville, MD 20852-3804

Dated: January 5, 2006

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